

Remarks

In the above-referenced Office Action, the Examiner rejected claims 1-13, 18-24, and 29 and withdrew claims 14-16, 25-28, and 30-50 as being drawn to a non-elected invention.

This Response cancels claims 2-13, 19-21, and 30-50 without prejudice to, or disclaimer of, the subject matter of these claims; amends claims 1, 18, and 22-23; and adds new claims 51-64. After entry of the foregoing amendments, claims 1, 18, 22-24, 29, and 51-64 (2 independent claims, 20 total claims) remain pending in the application. Reconsideration is respectfully requested.

Rejections under 35 U.S.C. § 112, ¶ 1

Claims 1-13, 18-24, and 29 stand rejected under 35 U.S.C. § 112, first paragraph. The Examiner contends that the specification does not enable any person skilled in the art to which it pertains to make the invention commensurate in scope with the claims. Applicants respectfully traverse this rejection.

Applicants submit that since claims 2-13 and 19-21 are cancelled herein, this rejection is rendered moot as to these claims.

Independent claim 1 is directed to a method comprising, *inter alia*, “culturing a dicotyledonous plant tissue comprising a meristematic region on a shoot multiplication (SM) medium to produce a multiple shoot culture from the tissue ... wherein said dicotyledonous plant tissue is squash, melon, watermelon, sunflower, or sugarbeet tissue.”

The Examiner acknowledges that Applicants’ specification is enabling for the transformation of “multiple shoot cultures of melon, watermelon, and squash ... and sugarbeet and sunflower” (Office Action, p. 2). However, the Examiner contends that the specification does not provide enablement for transformation methods other than *Agrobacterium*-mediated methods.

Applicants submit that the specification enables the claimed invention throughout its full scope. In particular, Applicants submit that, at the time of filing the present application, the skilled artisan would have appreciated that the step of “introducing a nucleic acid into a cell of the multiple shoot culture, thereby producing a transformed cell comprising the nucleic acid”

could be achieved by any of several standard transformation techniques, including, for example, *Agrobacterium*, biolistics, silicon carbide whiskers, PEG protoplasts, and sonication. Some of these methods are in fact discussed in one of the references noted by the Examiner (*i.e.*, Hansen *et al.*, 1999 Trends in Plant Science 4(6): 226-231).

The Examiner cites several references in support of the contention that the transformation of plant cells requires undue trial and error experimentation. Applicants respectfully submit that none of these references support the position that undue experimentation would have been required to practice the claimed invention.

Nam *et al.*, 1997 The Plant Cell 9: 317–333 (“Nam *et al.*”), reports on a study of ecotypes of *Arabidopsis* and the variation in their susceptibility to infection by *Agrobacterium*. It is somewhat perplexing that the Examiner chooses a reference concerning the transformation of *Arabidopsis*, which is a model dicot species for transformation and is, perhaps, the most transformed plant species in the world, to support the idea that some plant species are recalcitrant to transformation. Nam *et al.* describes, *inter alia*, a study of 11 *Arabidopsis* ecotypes which were transformed using 4 different *Agrobacterium* strains in a particular *in vitro* root assay. It was found that one of the ecotypes tested was recalcitrant to tumorigenesis by *Agrobacterium* strain A208. The focus of this work was, therefore, to actively seek *Arabidopsis* ecotypes that were recalcitrant to transformation by specific *Agrobacterium* strains in specific assays. The paper does not disclose whether transformation was successful with any of the other *Agrobacterium* strains. Thus, all this reference indicates is that a specific *Arabidopsis* ecotype, in a specific assay, is recalcitrant to transformation by a specific *Agrobacterium* strain. In other words, the reference describes what is very much an exception to the well-established rule.

Han *et al.*, 1997 Can. J. For. Res. 27: 464–467, describes the “high-frequency” transformation of cottonwoods by *Agrobacterium rhizogenes*. The abstract on page 464 states, “many species of *Populus*, particularly cottonwoods of sections Aigeiros and Tacamahaca, remain recalcitrant to transformation.” Page 464, column 2, line 8 states, “[o]ne possible explanation for its recalcitrance to transformation is the lack of an efficient regeneration system.” (Emphasis added). Furthermore, page 467, column 2, final paragraph states, “[w]e report high transformation efficiency for hybrid cottonwood, which has shown recalcitrance in our

transformation experiments with *A. tumefaciens*. The main obstacle in transformation appears to be targeting and isolating regenerable cells.” (Emphasis added). *Prima facie*, this reference indicates that the provision of transgenic cottonwoods was problematic not due to the transformation of a cottonwood cell *per se*, but, rather, due to the lack of a suitable regeneration procedure.

Chateau *et al.*, 2000 J. of Experimental Botany 51(353): 1961–1968, like Nam *et al.*, relates to the transformation of *Arabidopsis*, and, thus, the general arguments noted above with respect to *Arabidopsis* transformation apply equally here. Chateau *et al.* simply indicates that *Arabidopsis* transformation efficiencies may be improved following a phytohormone pre-treatment.

Kohli *et al.*, 1998 PNAS 95: 7203–7208, simply relates to a study of integration patterns following direct (biolistic) DNA transfer. The reference indicates that DNA transferred into plant cells by this method inserts at a single transgenic locus. *Prima facie*, this reference has no bearing on the transformation of plants cells *per se*.

Potrykus, 1990 Biotechnology 8(6): 535-542 (“Potrykus”), is simply a review of the state of the art of plant transformation and regeneration as of 1990, that is, over a decade ago. There have been substantial improvements in the technology between 1990 and the filing date of the instant application. For example, cereal plant cells are now routinely transformed by *Agrobacterium* methods, as indicated in Hansen *et al.*, 1999 Trends in Plant Science 4(6): 226-231 (“Hansen *et al.*”) at page 229, column 1.

Hansen *et al.* is a review of plant transformation and regeneration published in 1999. It provides a useful summary of the changes that occurred since Potrykus was published.

Applicants respectfully submit that the introduction of a nucleic acid into a plant cell, *per se*, is enabled by the specification and would not have required undue experimentation. Indeed, the variety of references noted by the Examiner, all of which were available at the time of filing the instant application, demonstrates that one skilled in the art would have been able to select any of several well-known transformation methods to “[introduce] a nucleic acid into a cell of the multiple shoot culture, thereby producing a transformed cell comprising the nucleic acid,” as

recited in Applicants claims. None of the references cited by the Examiner establishes otherwise. Thus, Applicants submit that the claimed invention is enabled throughout its full scope.

Independent claim 64 is directed to a method comprising, *inter alia*, “culturing a dicotyledonous plant tissue comprising a meristematic region on a shoot multiplication (SM) medium to produce a multiple shoot culture from said tissue; using *Agrobacterium* to introduce a nucleic acid into a cell of said multiple shoot culture, thereby producing a transformed cell comprising said nucleic acid ... wherein said dicotyledonous plant tissue is from a plant of any family selected from *Cucurbitaceae*, *Chenopodiaceae*, and *Asteraceae*.”

The Examiner acknowledges that the specification enables the generation of multiple shoot cultures and conditions that promote shoot elongation in plants belonging to the families *Cucurbitaceae* and *Chenopodiaceae* and in sunflower (*i.e.*, the family *Asteraceae*) (Office Action, p. 3). For this reason and the reasons set forth above regarding independent claim 1, Applicants submit that claim 64 is enabled throughout its full scope.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

Rejection under 35 U.S.C. § 103(a)

Claims 1-13, 18-24, and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Tuli *et al.*, U.S. Patent No. 6,242,257, filed May 22, 1997 (“Tuli”), in view of Rangan *et al.*, U.S. Patent No. 5,834,292, issued Nov. 10, 1998 (“Rangan”), and Jefferson *et al.*, EMBO J. 1987 6:3901-3907 (“Jefferson”). Applicants respectfully traverse this rejection.

Applicants submit that since claims 3-13, 18, and 19-21 are cancelled herein, this rejection is rendered moot as to these claims.

Independent claim 1 is directed to methods comprising, *inter alia*, “culturing a dicotyledonous plant tissue comprising a meristematic region on a shoot multiplication (SM) medium to produce a multiple shoot culture from the tissue ... wherein said dicotyledonous plant tissue is squash, melon, watermelon, sunflower, or sugarbeet tissue.”

Independent claim 64 is directed to a method comprising, *inter alia*, “culturing a dicotyledonous plant tissue comprising a meristematic region on a shoot multiplication (SM)

medium to produce a multiple shoot culture from said tissue; using *Agrobacterium* to introduce a nucleic acid into a cell of said multiple shoot culture, thereby producing a transformed cell comprising said nucleic acid ... wherein said dicotyledonous plant tissue is from a plant of any family selected from *Cucurbitaceae*, *Chenopodiaceae*, and *Asteraceae*."

Applicants submit that none of the cited references, either alone or in combination, discloses or suggests these elements. Since the references do not teach or suggest all of the elements of the claimed invention, a prima facie case of obviousness is not established.

Accordingly, the claimed invention is patentable over the cited references, and Applicants, therefore, respectfully request the withdrawal of the rejection under 35 U.S.C. § 103(a).

CONCLUSION

Pursuant to the foregoing remarks, Applicants respectfully submit that all of the pending claims fully comply with 35 U.S.C. § 112 and are allowable over the prior art of record. No new matter is added by this amendment. Any and all amendments to the claims that are not specifically referenced in the above Remarks are intended to be cosmetic in nature and are not made for reasons related to the patentability of the claimed invention. Entry of the amendments is respectfully requested.

Reconsideration of the application and allowance of all pending claims is earnestly solicited. Should the Examiner wish to discuss any of the above in greater detail or deem that further amendments should be made to improve the form of the claims, the Examiner is invited to telephone the undersigned at the Examiner's convenience.

Respectfully submitted,



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